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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 12192003

Application Number: 09/788,334
Filing Date: February 16, 2001
Appellant(s): CARLSON, THOMAS B.

Robert Hanson
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 14 October 2003.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is substantially correct. The changes are as follows:

Claims 1, 2, 5, 7-10, 12, 13, and 21-23 are allowed. Claims 3, 6, 11, 14-20, and 24-31 remain rejected and stand appealed. Claim 4 has been cancelled in the paper submitted by Appellant on 30 June 2003. In the Appeal Brief, Appellant indicates that it is not known if the amendment canceling claim 4 has been entered (page 2, 3rd full paragraph). The reason for this is that the last Office action, mailed 25 July 2003, indicated that claim 4 remained rejected. Appellant's first Appeal Brief and accompanying amendment, filed 30 June 2003, was not forwarded to the Examiner before the mailing of the last Office action on 25 July 2003. The Examiner was not aware of the papers filed on 30 June 2003, and the papers therefore were not considered before the last Office action was mailed on 25 July 2003.

Claims 3, 6, 11, 14-20, and 27-30 remain rejected under 35 U.S.C. 112, 2nd paragraph. The rejection is withdrawn from claims 22-25.

Claims 6, 11, and 24-31 remain rejected under 35 U.S.C. 112, 1st paragraph, as not being supported by an adequate written description. The rejection is withdrawn from claims 2-4.

Claims 27-30 remain rejected under 35 U.S.C. 112, 1st paragraph, for lack of enablement.

Claim 26 was objected to in the Office action mailed 25 July 2003, as being in improper dependent form for failing to further limit the subject matter of a previous claim. Appellant did not address this objection.

(4) Status of Amendments After Final

The Appellant's statement of the status of amendments after final rejection contained in the brief is incorrect.

The Appeal Brief indicates that an amendment under 37 CFR 1.116 was concurrently filed (page 3, 2nd full paragraph). However, no amendment was filed with the Appeal Brief submitted 14 October 2003. An amendment was filed with the first Appeal Brief filed on 30 June 2003. That amendment directed the cancellation of claim 4, and was entered.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 2, 3, 6, 11, 14-20, and 24-31 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

A substantially correct copy of appealed claims 3, 6, 11, 14-20, and 24-31 appears in Appendix 1 on pages 31-33 of the Appellant's brief. The minor errors are as follows: claim 17 in both Appendix 1 and Appendix 2 (pages 34-37 of Appellant's Brief, which provides a copy of all pending claims) contains a parenthesis in line 1. This is a typographical error that only appears in the Appeal Brief. Pending claim 17, as it is written in application 09/788,334, does not contain this parenthesis. Further, Appendix 2 includes claim 4, which has been cancelled.

(9) Prior Art of Record

5,523,520 Hunsperger et al. 06-1996

Eshed et al., "Less-Than-Additive Epistatic Interactions of Quantitative Trait Loci in Tomato", Genetics, Vol. 143 (August 1996), pp. 1807-1817.

Kraft et al., "Linkage Disequilibrium and Fingerprinting in Sugar Beet", Theoretical and Applied Genetics, Vol. 101 (2000), pp. 323-326.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 3, 6, 11, 14-20, and 27-30 on appeal stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 3: the recitation, "further defined as an essentially homogeneous population of seed" renders the claim indefinite. Claim 2 reads, "A population of seed of the corn variety I015011, wherein a sample of the seed of the corn variety I015011 was deposited under ATCC Accession No. PTA-3224." Claim 3 is directed to "The population of seed of claim 2, further defined as an essentially homogeneous population of seed." The "further defined as" recitation in claim 3 renders the claim indefinite because it is unclear what affect this recitation has on the scope of the claim. The recitation, "A population of seed of the corn variety I015011" in claim 2 indicates that the population of claim 2 is a homogeneous population of seed of corn variety I015011. The recitation, "essentially homogeneous," in claim 3 would thus appear to be superfluous. However, reading the claims in light of the specification, lines 17-22 of page 5 indicate that inbred seed can form less than 100% of an essentially homogeneous population. Thus, the scope of claim 3 is unclear. Note that if claim 3 were amended to read, "An essentially homogeneous population of corn seeds consisting essentially of the seed of claim 1", the claim would have a definite meaning.

Appellant's argument and Examiner's response:

Appellant argues that while claim 2 is directed to a population of seed of corn variety I015011, it is not necessary that the population be essentially homogeneous. Appellant provides the definition for "population" from the Meriam-Webster on-line dictionary (Exhibit A), and argue that the relevant definition is "a body of persons or individuals having a quality or characteristic in common. Appellant also provides the definition for "homogeneous" (Exhibit B), which is "of uniform structure or composition throughout", and argues that a population of seed of corn variety I015011 may could be non-uniform in size or shape, yet have the common

quality of being a corn plant of variety I015011. Appellant argues that as such, claim 3 is in proper dependent form and is not indefinite. (Appeal Brief, paragraph bridging pages 6-7).

Appellant appears to be arguing that the recitation, "essentially homogeneous," in claim 3 indicates that the individual I015011 seed of the claimed population share a uniform structure, for example size and shape. However, the issue does not concern the size and shape of individual seeds. Further, Appellant's argument is inconsistent with the discussion of "essentially homogeneous population of inbred seed" in the specification. Page 5, lines 15-21, of the specification states, "Essentially homogeneous populations of inbred seed are those that consist essentially of the particular inbred seed, and are generally free from substantial numbers of other seed, so that the inbred seed forms between about 90% and about 100% of the total seed, and preferably, between about 95% and about 100% of the total seed. Most preferably, an essentially homogeneous population of inbred corn seed will contain between about 98.5%, 99%, 99.5% and about 99.9% of inbred seed, as measured by seed grow outs." This definition does not concern the size and shape of the particular inbred seed of an essentially homogeneous population of inbred seed, but rather addresses the percentage of the population that is made up of the particular inbred seed versus other varieties of seed. The scope of claim 3 is unclear because the essentially homogeneous population of that claim can comprise varieties of seed other than I015011, whereas the population of claim 2 is directed to a single variety of seed, that of corn variety I015011. As noted above, amending claim 3 to read "An essentially homogeneous population of corn seeds consisting essentially of the seed of claim 1", would obviate this rejection.

In claim 14: the recitation "An essentially homogeneous population of corn plants produced by growing the seed of the corn variety I015011" in lines 1-2 renders the claim indefinite. The I015011 seed can only produce I015011 plants. The claim does not mention any other type of seed. The population can therefore only consist of I015011 plants. It is then not clear why the population is referred to as "essentially homogeneous," since such populations can comprise more than one variety of plant. Amending claim 7 to read, "An essentially homogeneous population of corn plants produced by growing a population of corn seed consisting essentially of the seed of corn plant I015011, a sample of said seed having been deposited under ATCC Accession No. PTA-3224" would obviate the rejection.

Appellant's argument and Examiner's response:

Appellant argues that a population need not be essentially homogeneous (Appeal Brief, paragraph bridging pages 7-8). However, the claim clearly states, "An essentially homogeneous population of corn plants..."

Appellant again argues that a population of plants grown from I015011 seed could vary in size or other characteristics due to environmental or other conditions, but still be population produced by growing I015011 seed (Appeal Brief, paragraph bridging pages 7-8).

However, again, Appellant's interpretation of "essentially homogeneous population" differs from that provided on page 5, lines 15-21 of the specification, which explains how other varieties of seed may be in an essentially homogeneous population of a particular variety of seed. It is rather well known in the art that, when referring to plants, the term "variety" is used to distinguish genetically distinct taxonomic groups below the species level. I015011 is a variety of corn plant. Corn plant "X" is another variety of corn plant, and is genetically distinct from

variety I015011. I015011 seed cannot produce "X" corn plants, but can only produce I015011 corn plants. It is not at all clear why Appellant is arguing that an "essentially homogenous population of corn plants" refers to the non-uniform nature of the same variety of corn plant, when the definition in the specification (page 5, lines 17-20) concerns the amounts of genetically different varieties of corn that can be in an essentially homogeneous population. Claim 14 indicates that growing only the seed of the inbred corn plant I015011 produces the corn plants of the essentially homogeneous population of corn plants. But if only one variety of seed is being grown, only one variety of corn plant can be produced. It therefore remains unclear why claim 14 is directed to an essentially homogeneous population of corn plants that, according to the specification, can comprise more than one variety of plant. If the population of claim 14 is to encompass only plants produced by growing I015011 seeds, as Appellants appear to be arguing, it is not clear why the claim is directed to an essentially homogeneous population of corn plants. The definition on page 5 also indicates that an essentially homogenous population of an inbred corn seed may be comprised of 100% of that seed. However, limitations of the specification cannot be read into the claims. As noted above, amending claim 14 to read, "An essentially homogeneous population of corn plants produced by growing a population of corn seed consisting essentially of the seed of corn plant I015011, a sample of said seed having been deposited under ATCC Accession No. PTA-3224" would obviate this rejection.

Appellant indicates on page 8, 1st full paragraph of the Appeal Brief that the rejection of claim 21 under 35 U.S.C. 112, 2nd paragraph was made final. However, this rejection was withdrawn in the Office action mailed 25 July 2003.

In claims 6 and 11: the recitation "in accordance with" renders the claims indefinite. The meaning of this recitation is not exactly clear, and makes the metes and bounds of the claims unclear.

Appellant's Arguments and Examiner's Response:

Appellant provides the definition for "accordance" that appears in the on-line version of the Meriam-Webster Dictionary, one of which is "agreement, conformity" (Exhibit C). Appellant argues that the term therefore has a well known meaning in the art and its use in the claim is not indefinite (Appeal Brief, paragraph bridging pages 9-10).

It remains unclear whether the claimed inbred plant cell or plant has the SSR profile or the genetic isozyme typing profile of Tables 5 and 6. It is not clear, for example, what is meant by an SSR profile that is in conformity with the profile shown in Table 5. Is the SSR profile the same, or is it not the same, as that shown in Table 5? Would an SSR profile that generally follows the trend of the profile of Table 5, but which differs at one or a few loci, be considered in "conformity" or "in accordance" with the profile of Table 5? It is not clear what is meant by a marker profile that "agrees" with another marker profile. Are they the same or not? If the profiles are not exactly the same, then it is not clear what the differences are. If Appellants intend for the claimed inbred plant cell or plant to have the same profiles as those shown in Tables 5 and 6 for corn plant I015011, it is suggested that part (a) of claims 6 and 11 be replaced with --the SSR profile for corn plant I015011 shown in Table 5; and--, and that part (b) of the claims be replaced with --the isozyme typing profile for corn plant I015011 shown in Table 6--.

In claims 15, 17, and 20: the recitation "capable of expressing" in line 1 of claim 15 and line 2 of claims 17 and 20 renders the claims indefinite. The recitation does not make clear if the plant actually expresses the traits, or when or under what conditions the traits are expressed. It is suggested that the recitation in claim 15 be replaced with --having--, and in claim 20 with --has--. Similarly, the recitation "is capable of regenerating" in line 2 of claim 17 renders it indefinite. It is suggested that the recitation "the tissue is capable of regenerating plants capable of expressing" be replaced with --plants, when regenerated from said tissue culture, have--.

Appellant's Argument and Examiner's Response:

Appellant argues that the term "capable" is well known in the art and is thus fully definite, and that claim breadth is not indefinite. Appellant argues that one of skill in the art would understand whether a corn plant is capable of expressing all of the traits of corn plant I015011 by way of its biological deposit, and one would therefore ascertain whether a plant is capable of expressing all of the traits of I015011 based on direct comparisons (Appeal Brief, page 10, 1st full paragraph).

However, it is maintained that the recitation, "capable of expressing", renders the claim indefinite because the recitation can be interpreted to indicate that, while the plant has the capacity to express the characteristics, for some reason it may not. Certain characteristics of a plant are expressed only at certain times of its life cycle, and are incapable of being expressed at other times. The colors of flower parts such as silks, or fruit parts such as husks, are examples. The promoters of many genes conferring traits require a transcription factor to become active. Is a plant that has such a gene, but not the transcription factor, considered "capable of expressing" that gene, and the trait associated with that gene, and is such a plant encompassed by the claims?

Furthermore, traits such as plant height or yield are environmentally influenced. A particular value for plant height or seed yield observed in Appellant's tested growing environment might not be observed in another environment. The claim amendments suggested above particularly point out that the plant does have all of the morphological and physiological characteristics of I015011, while not requiring all of the characteristics to be expressed at all times of the plant's life cycle.

In claims 16 and 27: the claims appear to broaden the scope of the claims from which they depend, or raise doubts as to whether the corn plant of claim 16 must be male sterile and whether the corn plant of claim 27 has the traits of the corn plant of parent claim 5. Claims 16 and 27 add on a gene or locus to the genome of the plant of their parent claims. The specification does not define the plants expressing all the morphological and physiological characteristics of I015011 as being male sterile; in fact, the plant of claim 15 (from which claim 16 depends) is male fertile. Thus claim 16 cannot incorporate all the limitations of claim 15 because it is directed to a plant that is not male fertile. Claim 27 is indefinite for the same reasons as for claim 16- it is not clear if the plant of claim 27 has all of the characteristics of the plant of parent claim 5. There is no indication as to how the plants acquired the genes, and the plant of their parent claims does not possess the gene or locus. It is suggested that claim 16 be amended to recite that the plant was produced from the plant of claim 15, and to indicate how the cytoplasmic or nuclear gene conferring male sterility was introduced into the plant of claim 8. Claim 27 should be similarly amended.

Appellant's argument and Examiner's response:

Appellant argues that claim 16 adds a gene conferring male sterility, while claim 27 adds a single locus conversion, to the parent claim. Appellant argues that the claims contain a reference to the parent claim, contain a further limitation of the subject matter claimed in the main claim, and incorporate all elements of the claim from which they depend. Appellant argues that how the plants acquire the added elements is irrelevant to the scope or definiteness of the claims, as they are product claims, not process or product by process claims (Appeal Brief, paragraph bridging pages 10-11).

However, the claims do not incorporate all elements of their parent claims. The plant of claim 15 is male fertile. The plant of claim 16, however, is not male fertile. Therefore, claim 16 does not incorporate all elements of the claim from which it depends. Further, as the plant of claim 15 is male fertile, it is contradictory to say that claim 16 incorporates all elements of claim 15, yet is directed to a plant that is not male fertile. The single locus conversion of the plant of claim 27 does not have to be a gene that confers male sterility. However, as the locus may encode any trait, and can affect the plant of parent claim 5 in any manner, the plant of claim 27 does not have to have all of the traits expressed by the plant of claim 5. The plant of claim 27 then would not have all of the limitations of the plant of claim 5. Claim amendments are suggested at the end of this Examiner's Answer, in Appendix A.

The rejection of claim 18, in regards to the recitation, "derived from", is withdrawn, upon further consideration of Appellant's arguments. However, note that claim 18 remains rejected because it is dependent on claim 17.

The rejection of claim 19, in regards to the recitation, "the regenerable cells comprise protoplasts", is withdrawn, upon further consideration of Appellant's arguments. However, note that claim 18 remains rejected because it is dependent on claim 17.

The rejection of claim 22, for reciting a new process different from its parent claim, is withdrawn upon further consideration of Appellant's arguments.

In claim 28: the article "a" in the recitation "wherein the single locus was stably inserted into *a* corn genome" (emphasis added) renders the claim indefinite. The recitation does not make clear if the genome is that of I015011 or that of a different corn plant.

Appellant's Arguments and Examiner's Response:

Appellant notes that the single locus may or may not have been directly inserted into the genome of the claimed plant, but argue that this does not render the claim indefinite, because the single locus may have been inserted into a parent I015011 plant and self pollinated to produce the claimed plant. Appellant argues that the single locus need not have been directly inserted into the genome of I015011, and that loci that are stably inserted into a corn genome are also stably inherited (Appeal Brief, page 12, last paragraph).

However, a parent plant of inbred variety I015011 is itself I015011. Therefore it remains unclear, what other genomes are encompassed by "a corn genome", and how does it relate to the plant of claim 28? Further, if the single locus is transformed into an entirely unrelated plant and introduced into I015011 by crossing and selection, the resultant plant would have the single locus but it would not otherwise be exactly the same as I015011.

In claim 30: the recitations, "yield enhancement," "improved nutritional quality," and enhanced yield stability" are relative terms that have no definite meaning, and make the metes and bounds of the claim unclear.

Appellant's argument and Examiner's response:

Appellant argues that those of skill in the art understand all the terms and there is no prohibition upon the use of relative terms. Appellant argues that the terms must be read in the context of the claim in which they are found, that the subject claim recites a single locus that confers the traits of yield enhancement, improved nutritional quality, and enhanced yield stability, and that it is understood that the enhancement of yield or yield stability and improvement in nutritional quality is relative to a plant lacking the single locus. The metes and bounds of the claim would thus be fully understood by one of skill in the art (Appeal Brief, page 13, 1st full paragraph).

However, relative terms cannot be used if the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Here, the specification does not provide any such standard. What one may consider an enhancement or improvement over a plant lacking the single locus, may not be considered so by another, in the absence of a defined standard that must be met. Further, what nutritional qualities are contemplated, and how are they improved?

Claims 6, 11, and 24-31 on appeal stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is withdrawn from claims 2, 3, and 14 upon further consideration of Appellant's arguments. Claim 4 is cancelled.

The claims are broadly drawn towards a corn plant, or a cell thereof, wherein the plant is produced by growing seed of corn variety I015011, wherein the corn plant has an SSR profile or an isozyme typing profile that is in accordance with any of the profiles, for three different plants, shown in Tables 5 and 6, respectively; any hybrid corn seed produced by crossing corn plant I015011 with any second, distinct inbred corn plant; any hybrid corn plant produced by growing said hybrid seed; inbred corn plant I015011 further comprising any single locus conversion; a method of producing any inbred corn plant derived from corn variety I015011 comprising crossing I015011 plants with any second corn plant, and crossing the progeny with itself or any other plant to produce further progeny.

The specification describes numerous morphological and physiological characteristics, and provides the names of SSR markers and isozyme loci, of inbred corn plant I015011 (page 24, lines 2-5; Tables 1 and 2, pages 24-26; page 26, line 10 to page 27, line 16; Table 3, pages 27-29; Table 5, pages 60-62; Table 6, pages 62-63). The specification indicates that a deposit of 2500 seeds of I015011 has been made with the American Type Culture Collection, under the Accession No. PTA-3224, under the terms of the Budapest Treaty (amendment to page 29, lines 8-16, of the specification, in the paper received 18 February 2002, page 3). It is noted that all restrictions to the availability of the public to the deposited seed will be irrevocably removed

upon the granting of a patent (Declaration of Biological Culture Deposit, submitted with the papers received 18 February 2002). The specification also describes morphological traits, names of SSR markers and isozyme loci, of a single hybrid corn plant, designated "6017147," produced by crossing I015011 with an inbred corn plant designated "91INH2" (page 53, lines 14-20; Table 4, pages 56-57; Table 7, pages 63-65; Table 8, pages 65-66).

A review of the full content of the specification indicates that seed of inbred corn plant I015011, and hybrid seed produced by crossing an I015011 plant with any other corn plant, are essential to the operation and function of the claimed invention. A search of seed of inbred corn plant I015011 indicates that it is novel and unobvious.

A review of the language of claims 24-26 indicates that the claims are drawn to a genus, i.e., any and all hybrid corn seeds, and the hybrid corn plants produced by growing said hybrid seeds, wherein the hybrid seeds are produced by crossing inbred corn plant I015011 with any second, distinct inbred corn plant. Variation is expected in the complete genomes and phenotypes of the different hybrid species of the genus, since each hybrid has one non-I015011 parent that is not shared with the other hybrids. Each of the hybrids would inherit a different set of alleles from the non-I015011 inbred parent. As a result, the complete genomic structure of each hybrid, and therefore the morphological and physiological characteristics expressed by each hybrid, would differ.

The specification does not describe any hybrid corn plants produced by crossing I015011 with any other inbred corn plant, except for the hybrid designated "6017147" (page 56, line 1 to page 57, line 5). The descriptions of I015011 and 6017147, however, do not provide any information concerning the description of all other hybrids. There is no evidence on the record

of any relationship between the structure of the complete genome of hybrid 6017147 and the complete genome of other hybrids. Hybrids produced by crossing I015011 with other, distinct inbred corn plants would, of course, produce plants that do not express the same traits as I015011, and hybrids produced by crossing I015011 with distinct inbred corn plants other than 91INH2 also would not express the same traits as 6017147. The descriptions of I015011 and 6017147 do not provide any information concerning the morphological and physiological characteristics of other plants. In view of these considerations, a person of skill in the art would not have viewed the teachings of the specification as sufficient to show that the Applicant was in possession of the claimed genus of hybrid seeds and plants produced therefrom.

The specification also indicates that Table 5 provides names of loci where the SSR markers supposedly reside, for three different corn plants, and a numerical value for each marker that represents numbers of base pairs (specification, page 58, line 2 to page 59, line 24). The specification indicates on page 59, lines 13-14, that the SSR analyses were conducted at Celera AgGen, and on page 62, following Table 5, that primers used in the analyses are also from Celera AgGen.

Claims 6 and 11 are drawn to an inbred corn plant, or a cell thereof, wherein the plant is produced by growing a seed of inbred corn variety I015011, said plant or cell thereof comprising an SSR genetic marker profile in accordance with the profile shown in Table 5, or a isozyme typing profile in accordance with the profile shown in Table 6.

However, while names and numbers of base pairs of loci of the SSR markers are provided, the actual nucleotide sequences that make up the markers are not provided. Names of loci alone do not describe the structures of the markers themselves. Without a description of the

sequences of the markers, one cannot confirm their presence. Table 6 provides names of loci where isozyme markers reside, for three different corn plants, and a numerical value that represents the numbers of alleles at isozyme loci types. It is noted that 9 of the 12 isozyme markers of I015011 in Table 6 are also found in at least two other corn varieties, those of the other plants of Table 6. Hence, the markers in Table 6 are not adequate to distinguish the claimed hybrids from other corn plants, as other corn plants contain almost all of the same markers.

The specification also indicates that single locus converted plants are defined as plants which are developed by a plant breeding technique called backcrossing wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in addition to the characteristics conferred by the single locus transferred into the inbred via the backcrossing technique. A single locus may comprise one gene, or in the case of transgenic plants, one or more transgenes integrated into the host genome at a single site (locus). The specification contemplates numerous different single loci involved in expressing various traits (pages 31-35). The specification provides the origin and breeding history of a single exemplary single locus converted plant, in which the trait of cytoplasmic male sterility was introduced not into corn plant I015011, but into another corn inbred (pages 35-36).

Claims 27-30 are drawn towards I015011 plants further comprising a single locus conversion, or wherein the single locus was stably inserted into a corn genome by transformation. A review of claims 27-30 indicate that they encompass a genus of corn plants, each species of which can differ in the morphological and physiological traits that they can express, since they would comprise different single locus conversions. Claims 27-30 also do not

place any limitation on the trait conferred or affected by the single locus conversion. However, the specification does not describe identified or isolated single loci for all corn plant traits. While the specification, on pages 29-32, recites traits that are contemplated to be introduced into LIZL5, single loci governing all of these traits have not been identified. For example, single loci that govern yield enhancement or enhanced yield stability, recited in claim 28, are not described. Claims 27-30 also broadly encompass single loci that have not been discovered or isolated. A single locus governing "industrial usage" (recited in the specification on page 31, line 9), for example, is not known in the art. Further, a locus, for example one that encodes a transcription factor, can affect more than just one gene, and multiple traits. Such plants would express different morphological and physiological traits from I015011, which are not described.

The specification also indicates that the present invention provides a method of producing an inbred corn plant derived from corn plant I015011. The method comprises (a) crossing a I015011 plant with a second corn plant to produce a progeny plant, (b) crossing the progeny plant with itself or a second plant to produce a seed of a progeny plant of a subsequent generation, (c) crossing the plant produced by growing that seed with itself or a second plant, and repeating steps (b) and (c) for an additional 3-10 generations (page 10, line 18 to page 11, line 4; page 49, line 20 to page 52, line 24).

Claim 31 is drawn to a method of producing an inbred corn plant derived from corn plant I015011. The method comprises (a) crossing a I015011 plant with a second corn plant to produce a progeny plant, (b) crossing the progeny plant with itself or a second plant to produce a seed of a progeny plant of a subsequent generation, (c) crossing the plant produced by growing that seed with itself or a second plant, and repeating steps (b) and (c) for an additional 3-10

generations. A review of the claim indicates that hybrid progeny of corn plant I015011 are required to perform further crosses, and that progeny of subsequent generations can be further outcrossed with different corn plants. The hybrid progeny of corn plant I015011, and progeny plants of subsequent generations, are essential to operate the claimed method. Substantial variation is expected among the progeny plants, as the identities of the second corn plant to which I015011 may be crossed and to which progeny plants may be crossed, are not limited.

The specification teaches a single hybrid progeny corn plant, designated 6017147, produced by crossing inbred corn plant I015011 with inbred corn plant 91INH2 (page 53, lines 17-20). However, the specification does not describe any other hybrid corn plant, or any progeny corn plants of subsequent generations, as discussed above. Hybrid plant 6017147 is not representative of all other hybrid progeny corn plants, as other hybrid progeny plants do not have both of the same parents as 6017147. The Federal Register (64 Fed. Reg. 71427, 71428 (1999), Comment No. 4) indicates that a suggestion was made that the written description guidelines should distinguish between claims to processes whose patentability depends on the compositions used in them, as opposed to those whose patentability rests in the steps of the process itself, and that this suggestion was adopted. Accordingly, claim 31 includes steps in which hybrids, produced by crossing inbred corn plant I015011 with a second, different corn plant, are involved in crosses. The patentability of the method of claim 31 does not lie in the method steps, which require the simple acts of crossing corn plants, allowing progeny seed to be produced, and growing progeny plants from the seed, but rather in the compositions used in the method. The method of claim 31 is not described, as the specification does not sufficiently describe the genus of hybrid plants, and or any progeny of subsequent generations, for the reasons discussed above.

Given the breadth of the claims encompassing all hybrid corn plants and seeds produced by crossing I015011 to any other corn plant, I015011 plants comprising any single locus conversion, and the description in the specification of only I015011 and a single hybrid, 6017147, it is submitted that the specification fails to provide an adequate written description of the multitude of corn plants and their parts encompassed by the claims.

Appellants' Arguments and Examiner's Response:

Appellant argues that the hybrid seeds and plants of claims 22-24 (it is assumed that Appellant is actually referring to claims 24-26) are described because they have I015011 as a parent and therefore contain a copy of the same genome as corn plant I015011, and that they have inherited half of their genetic material from I015011 (Appeal Brief, paragraph bridging pages 14-15).

First, the Examiner would like to address a statement made by Appellant that may be a point of confusion. Appellant states, "All of the claimed hybrid plants having I015011 as a parent will therefore contain a copy of the same genome as corn plant I015011" (emphasis added; Appeal Brief, paragraph bridging pages 14-15). This statement may be confusing, as it can be interpreted to mean that the entire genome of any of the claimed hybrids is identical to the entire genome of I015011. Since inbred corn plant I015011 must be crossed with a different corn plant to produce the claimed hybrids, the claimed hybrids cannot have entirely the same genome as I015011. It appears to the Examiner that Appellant did not intend to indicate that all of the claimed hybrid plants have entirely the same genome as I015011, as Appellant then

immediately states, "That is, because I015011 is an inbred corn plant, hybrid corn plants derived therefrom will have as half of their genetic material the same genetic contribution of corn plant I015011..." (emphasis added), which correctly indicates that all hybrids would inherit one-half, not all, of their genome from I015011.

The Examiner maintains that the claimed hybrids will not have the same morphological and physiological characteristics as I015011. I015011 can be crossed with any other inbred corn plant to produce the claimed hybrids. The claimed hybrids then will express a combination of morphological and physiological characteristics that are different from each other, and which are also different from those expressed by I015011. That all hybrids will inherit half of their alleles from I015011 does not provide any information concerning the morphological and physiological characteristics that will be expressed by the claimed hybrids. The specification does not correlate any genes of I015011 with any of the traits that it expresses. Further, the claimed hybrids will inherit one allele for every gene from the other, unidentified and undescribed parent plant. The specification does not describe how those alleles inherited from I015011, or how the products of those alleles, will be affected by or interact with the alleles or their products inherited from the other parent. The expressed gene products will depend on the combination of the two alleles from each parent at each locus, whether the allele is dominant or recessive, and on the epigenetic effects of other genes. The fact that any hybrid plant will inherit half of its alleles from I015011 then does not provide sufficient description of the morphological and physiological characteristics expressed by the claimed hybrid plants.

For example, if I015011 carries two recessive alleles for insect resistance, it will be susceptible to insects. If it is crossed to another inbred with a recessive allele at that locus, the hybrid will also be susceptible to insects. If the other chosen inbred has a dominant allele at that locus, the hybrid will be insect resistant, if simple Mendelian genetics governs the expression of this trait. Each inbred possesses thousands of genetic loci governing thousands of traits, including silk color, lodging resistance, leaf color, stalk color, disease resistance, stalk stiffness, waxy starch, days to maturity, etc., with a dominant or recessive allele at each locus. It is clear that the mere provision of one-half of the hybrid's genetic complement being inherited from I015011 is woefully inadequate to describe the resultant hybrid, either genetically or morphologically.

Appellant also argues that the entire genetic contribution of corn plant I015011 is described by way of deposit of seed of I015011 with the ATCC, and believes that this represents a description of concrete and identifiable structural characteristics defining the claimed hybrid plants and distinguishes them from other plants. In support, Appellant cites the decision of *Enzo Biochem, Inc. v. Gen-Probe Inc.*, for holding that a biological deposit constitutes a written description of the deposit material (Appeal Brief, paragraph bridging pages 14-15). However, in the patent considered in that decision, the deposited material corresponded exactly to one of the claimed products. The appeals court remanded the case for the district court to make findings on whether there was a correlation between the structure of the deposited material and the function of the variant material also claimed. Here, as in *Enzo*, the deposited inbred does not correspond exactly to the claimed hybrid. However, the functions of the claimed hybrid plants have not been correlated to the half of their genetic material originating from the deposited I015011 seed.

The function of the plant grown from an I015011 seed is correlated with the structure of its entire genome, not just one half. The function of the claimed hybrid plants grown from the claimed hybrid seeds is correlated with the structures of their entire genomes, not just the alleles inherited from I015011. Further, half of the alleles of the hybrid are inherited from the other parent, and are not described by the deposited I015011 seed. Therefore, the claimed hybrids do not have the same, complete genetic structure and function as that possessed by the deposited I015011 seed, as discussed above.

Appellant continues, citing the decision of *The Regents of the University of California v. Eli Lilly and Co.*, for noting that a name alone does not satisfy written description if structural features commonly possessed by members of the genus are not defined. Appellant argues that here, all of the members of the claimed genus of hybrids having I015011 as one parent share the identical feature of having the genetic complement of I015011 (Appeal Brief, page 15, 1st full paragraph). However, in *Eli Lilly*, the members of the genus shared a common function. In the instant application, the specification does not describe the function (i.e., morphological and physiological traits) of the claimed hybrids, and does not correlate the function of the hybrids with the structure of the genetic complement of I015011. Furthermore, the genetic complement of the other unknown parent has not been described, and hence Appellant has not provided a written description of the multitude of possible hybrid corn plants that would result from crossing the deposited inbred I015011 with any and all other inbred or hybrid corn plants.

Appellant argues that the claimed F1 hybrid plants having I015011 as one parent will share the same genetic complement from I015011, and are readily identifiable by the genetic marker analysis in Tables 5 and 7. Appellant argues that hybrid corn plant 6017147 has the SSR

genetic marker profile of I015011 and includes the genetic markers from the second parent plant, and that this will be true for any other hybrid plant having I015011 as one parent, save for "an occasional difference at a locus due to spontaneous genetic rearrangements" (Appeal Brief, paragraph bridging pages 15-16). However, while all of the claimed hybrids will inherit the SSR marker profile of I015011, they will not inherit the same genetic markers from the other parent as did hybrid 6017147, because they will have different parents, having different markers. The SSR marker profiles of the other parents are not described. Further, the description of corn plant 6017147 does not describe the morphological and physiological traits of all other corn plants that can be produced by crossing I015011 to any other corn plant. One skilled in the art cannot identify the morphological and physiological characteristics of corn plant 6017147 that will be expressed by all other members of the genus, nor can one identify the characteristics that will be different.

Further, while hybrid 6017147 has inherited the SSR marker profile of I015011, the specification does not describe the traits that are correlated with these markers. The traits expressed by 6017147 are not solely due to the presence of the alleles associated with the SSR markers inherited from the I015011 genome, or the genetic contribution of I015011, as discussed above. Further, written descriptions of each of the SSR and isozyme markers are not provided. The markers represent specific nucleotide sequences. While the markers are named, this is not sufficient to describe the nucleotide sequences that they represent. Further, none of these markers have been linked to any expressed traits.

It is also noted that the specification does not describe the sequences of the primers that were used to produce this SSR profile. The specification indicates on page 59, lines 13-14, that

the SSR analyses were conducted at Celera AgGen, and on page 62, at the bottom of Table 5, that primers used in the analyses are also from Celera AgGen. However, without a description of the sequences of the SSR markers, one cannot confirm the presence of the same SSR markers in any plant.

It is also noted that 9 of the 12 isozyme markers of I015011 in Table 6 are also found in at least two other corn varieties, those of the other plants of Table 6. Hence, the markers in Table 6 are not adequate to distinguish the claimed hybrids from other corn plants, as other corn plants contain almost all of the same markers.

Appellant continues, arguing that the second plant that is used to make the claimed hybrids is irrelevant, as any second plant capable of reproduction may be used to make the hybrid. Appellant argues that the claims cannot be said to lack written description for the second genetic complement, particularly given that hundreds or even thousands of different inbred corn lines were well known to those of skill in the art. Appellant points to the more than 195 patents issued for corn varieties as support, and argues that any one of these corn plants could be used to produce an F1 hybrid plant having I015011 as one parent, and each of these would share the genetic complement of I015011 (Appeal Brief, page 16, 1st full paragraph and paragraph bridging pages 16-17).

However, again, it is the interaction of the products of all of the alleles of the claimed hybrids, not just the products of the alleles inherited from I015011, which determine the traits of the claimed hybrids. Each parent contributes one set of chromosomes to the hybrid progeny, and each set of chromosomes comprises one allele for each gene at every locus in the genome, wherein alleles are alternate forms of the same gene that occur at a given locus. A phenotypic

trait of the plant results from the expression of the two sets of alleles. The resulting phenotype of the plant depends on how each allelic product interacts with the corresponding allelic product inherited from the other genome, as well as how each gene product interacts with other gene products in the genome. Some alleles of the same gene are dominant to others. The interaction of nonallelic genes by epistasis also affects the phenotype, and quantitative traits are determined by the combined effects of multiple genes. Given that a claimed hybrid corn plant comprises a set of alleles inherited from each parent and these two sets of alleles interact in a variety of ways to determine the hybrid's morphological and physiological traits, one cannot correlate the alleles inherited from I015011 alone, with the phenotype of the hybrid progeny. Thus, the deposit of I015011 seeds and the recitation of some phenotypic characteristics of corn plant I015011 is not sufficient to provide an adequate written description of all hybrid progeny that may be produced by crossing I015011 with a second, distinct corn plant. Appellant would have one believe that only half of a genome is sufficient to describe a plant. Yet, if only half of the genome of I015011 was deposited, it would not have been enough to describe its full genome, as discussed above.

Appellant then returns to the genetic marker data, alleging that the Action (presumed to be the Office action mailed 23 January 2003) attempts to downplay the significance of the genetic marker data in the specification, that no effort was made to show that any substantial number of marker loci actually are shared by other plants (Appeal Brief, page 17, 1st full paragraph). However, the specification shows that at least two other inbred corn plants, 2FACC and FBLL, share many of the same SSR loci (see Table 5). Further, the specification does not explain why the SSR data of inbreds 2FACC and FBLL were chosen for comparison with that of

I015011 in Table 5, how related these inbreds are to I015011, and hence how useful the SSR markers are for distinguishing different corn lines. Also, the specification does not mention anything concerning the traits expressed by the 2FACC and FBLL plants, and how similar those traits are to the combination of traits expressed by I015011. Further, is a comparison to only two inbreds sufficient to establish that the set of SSR and isozyme markers in Tables 5 and 6 can distinguish plants as having I015011 as a parent from those that do not? Given that 2FACC and FBLL share many of the SSR markers possessed by I015011, is the number of markers statistically significant to distinguish this genome from all other genomes? Even if the number of markers is sufficient, the specification fails to correlate any function, or trait, expressed by I015011, or the claimed hybrids, with any of the markers.

Appellant argues, regarding the availability of genetic markers or the primers used to detect the markers, that the service used to detect SSR markers is commercially available to the public, that SSR and other genetic marker systems that are well known may potentially be used, as described in the specification on pages 58-59 (Appeal Brief, page 17, 1st full paragraph). However, that the service used to detect SSR markers is currently commercially available is not a guarantee that it will remain so for the life of a patent issuing from the application. Further, the specification at pages 58-59 only provides a general discussion of other types of genetic markers, and does not describe any actual markers possessed by corn plant I015011.

Appellant next argues, in response to the Examiner's previous arguments that the morphological and physiological characteristics of the hybrids have not been described, and that the manner in which the genes inherited by the hybrids would be expressed or interact has not

been shown, that the Examiner's position misses the point that Appellant has gone one step further by describing the claimed hybrid plants at the genetic level. Appellant asserts that a better description could not be made than at the genetic level (Appeal Brief, paragraph bridging pages 17-18). However, again, Appellant is attempting to describe the claimed hybrids by only half of their genome. Appellant has deposited I015011 seed and, by extension, the I015011 genome, since the cells of the I015011 seed contain the I015011 genome. The claimed hybrids inherit only half of this genome, and the claimed hybrids do not have all of the same functions as those possessed by I015011. Given the genetic composition at each locus of the second inbred chosen as the hybrid's parent, the resultant hybrid may even have fewer than one-half of the traits exhibited by I015011.

The specification also provides the locus of many SSR and isozyme markers in the genome of I015011. However, as discussed above, the specification does not correlate any function of the claimed hybrids with this genetic information. The specification does not correlate any traits with any genes or molecular markers of I015011, and therefore the claimed hybrids. Further, while I015011 seed has been deposited, none of the hybrid seeds, which produce plants having traits and functions that are different from I015011, have been deposited.

Appellant continues, arguing that the law makes no distinctions regarding the manner in which applicant chooses to describe claimed compositions (Appeal Brief, page 18, 1st full paragraph). However, the Examiner has not limited Appellant to describing the claimed composition in any specific manner. Appellant argues that the genetic complement of parent plant I015011 that will be comprised in the claimed hybrid plants has been described by way of

the SSR and isozyme genetic marker profiles in Tables 5-8. However, as discussed above, while loci where these markers are located are identified, the sequences of the markers, or of primers used to locate them, are not described, nor are any functions of any alleles that may be associated with the markers described.

Appellants repeats the argument that a further description of the claimed hybrid plants is provided in the specification by way of hybrid 6017147, and believes that this plant is representative of hybrids produced using I015011 as one parent, each of which comprise the genetic complement of the parent corn plant (Appeal Brief, paragraph bridging pages 18-19). Appellant argues that Table 4 provides performance comparisons with other hybrid varieties (Appeal Brief, paragraph bridging pages 18-19). However, Table 4 provides some morphological traits expressed by hybrid plant 6017147. A table providing performance comparisons with other hybrid varieties is not in the specification. Appellant argues that the information of Table 4 combined with the SSR and isozyme marker profiles in Tables 7 and 8, and the description of I015011 and the shared structure among the hybrids is more than adequate to describe the claimed subject matter (Appeal Brief, paragraph bridging pages 18-19). However, again, hybrids that do not share both of the same parents will not have the same traits. The morphological traits Table 4 and the performance of hybrid 6017147cannot be extended to any other hybrid plant that does not have both of the same parents, and are not representative of all hybrids produced using I015011 as one parent.

Regarding claims 6 and 11: these claims were included in this rejection because the SSR and isozyme markers mention in Tables 5 and 6 are not described, for the reasons discussed above. Appellant argues that no basis has been provided for the allegation that written

description for the markers in Tables 6 and 7 is lacking (Appeal Brief, pages 19, 1st full paragraph). Appellant argues that the profiles are recited and the claims claim nothing more than what is provided in the tables. Appellant argues that the SSR markers were from Celera AgGen, Inc., and that isozyme markers are well known and isozyme analysis has been used for decades (Appeal Brief, pages 19, 1st and 2nd full paragraphs).

Table 5 provides names of loci where the SSR markers supposedly reside, and a numerical value that represents base pairs (specification, page 59, line 22). Table 6 provides names of loci where isozyme markers reside, and a numerical value that represents the numbers of alleles at isozyme loci types (specification, page 62, lines 14-15). The Office action mailed 25 July 2003 indicated that while names of loci are provided, names are not sufficient to describe the markers. Without a description of the sequences of the markers, one cannot confirm their presence. Further, claims 6 and 11 indicate that the claims plant or cell has the SSR profile or the isozyme profile. The genome of the cells of the I015011 seed deposited with the ATCC has both the SSR profile and the isozyme typing profile shown in Tables 5 and 6 for that plant. No plant is described in the specification that has one genetic marker profile but not the other.

Regarding claims 27-30, drawn towards corn plant I015011 containing single locus conversions: Appellant appears to be arguing that the specification describes such plants, simply because the definition of "single locus converted plants" provided in the specification indicates that such plants possess essentially all of the desired morphological and physiological characteristics of plant I015011 in addition to the characteristics conferred by the single locus transferred. Appellant argues that because the specification indicates that the claimed plants possess "essentially all of the desired morphological and physiological characteristics of [the

single gene converted plant]", that they have more than adequately described such plants (Appeal Brief, page 20, 1st full paragraph). However, the specification does not describe any and all single locus conversion traits, nor the source of all of said traits. The traits conferred by the single locus may also change one or more of the traits expressed by I015011, depending on what the locus encodes. A single locus whose product confers male sterility, for example, will change a trait of inbred corn plant I015011, rather than adding an additional trait. Further, the descriptions of plants that express "essentially" all of the "desired" characteristics of I015011 are not described. The definition indicates that the plants possess the "desired" characteristics of I015011. The "desired," as opposed to the "undesired," traits are not described.

Appellant cites *In re Gosteli* for indicating that the written description requirement does not require an applicant to describe exactly the subject matter claimed, but that the description must clearly allow persons of ordinary skill in the art to recognize what is claimed (Appeal Brief, page 20, 1st full paragraph). However, the specification does not describe the traits expressed by all of the claimed plants, nor what set of traits are present in all of the claimed plants to allow persons of ordinary skill in the art to recognize the claimed plants. The claimed genus reads on a multitude of I015011 plants further comprising an additional single locus, and having a multitude of different morphological and/or physiological traits. As discussed, the specification does not describe plants that express only some or "desired" traits that are expressed by I015011, or how to distinguish such plants from I015011. Further, single loci, for example those encoding a transcription factor, may affect one or more traits expressed by I015011. The claimed plant then may not express all of the "desired" traits of I015011. Such plants are not described by the specification.

In response to the issue raised in the previous Office actions that the claimed plants encompass introducing genes, or single loci, that have yet to be discovered, Appellant argues that undiscovered genes are not claimed, and that the fact that a given gene could be isolated in the future and introduced as a single locus conversion is irrelevant, because it is the single locus conversion of corn plant I015011 that is claimed (Appeal Brief, paragraph bridging pages 20-21). However, if a gene has not been discovered or isolated at the time the instant application was filed, Appellant cannot be in possession of a corn plant into which this gene was deliberately introduced. Furthermore, at least claim 30 explicitly recites undiscovered genes, since single genes that alone govern "yield enhancement" or "enhanced yield stability" have not been discovered.

Appellant continues, arguing that under the Examiner's reasoning, any claim could be read to encompass subject matter yet to be invented and therefore not described. For example, a corn plant transformed with a *Bacillus thuringiensis* gene (presumably encoding the insecticidal endotoxin) would be invalid because it would encompass corn varieties yet to be discovered (Appeal Brief, paragraph bridging pages 20-21). In this example, however, there is only one genetic structure that is relevant, that of the *B. thuringiensis* gene, and only one function, that of the insecticidal properties conferred by the product of the gene. A claim drawn towards a corn plant containing the gene may be described, if the structure and function of the gene is described. The corn plant comprising that gene has increased resistance against insects. In the instant application, the invention encompasses corn seed I015011 and the plant produced by it. The deposit of the seed satisfies the written description requirement for the I015011 seed, and the

functions of the plant are described in Tables 1-3. Another locus that is introduced into I015011 would amend its structure and functions.

Appellant argues that the Examiner supposedly ignored evidence submitted in a prior response that the specification recites numerous single locus traits with a publication reference or patent number. Appellant goes on to provide several examples (Appeal Brief, page 21, 1st full paragraph to page 23, 1st full paragraph). However, this argument was rebutted on pages 7-8 of the Office action mailed 23 January 2003. While the specification does cite references that describe numerous isolated genes, not all of the cited references actually teach that certain genes have been discovered or isolated. For example, the references cited in the specification do not describe isolated single genes or loci that confer yield enhancement or yield stability. If such single loci have not been discovered or isolated, Appellant cannot be in possession of I015011 plants comprising this single locus conversion. The claims broadly encompasses plant I015011 further comprising any single locus conversion, controlling any trait, including loci that have yet to be identified as independently controlling a trait. Appellant cannot be in possession of plants further comprising single loci that have yet to be identified. It is also noted that the Examiner is not asking Appellant to identify each and every gene known to man by name, but to identify the types of single loci, that alone control a trait, that have been identified. For example, many genes or single loci were known in the prior art that confer disease resistance, or herbicide resistance. In the Office action mailed 23 January 2003, it was suggested that the claims be amended to recite the types of single loci, not individual or specific loci names.

Appellant argues that techniques for introducing single locus traits by genetic transformation were well known (Appeal Brief, page 24, 1st full paragraph). That methods to

produce genetically transformed corn plants existed at the time of the invention is, of course, not disputed. However, methods for producing a product do not describe the product itself.

Proposed claim amendments that address the subject matter of instant claims 27-30, which were previously discussed with Appellant but not accepted, are presented in Appendix A, at the end of this Examiner's Answer. A discussion of why these proposed claims are deemed acceptable is also provided below.

Regarding claim 31: Appellant argues that the claim is a process claim that involves crossing corn variety I015011 according to the specified steps. Appellants indicate that, it appears to be the position of the Examiner that written description must be provided for each intermediate product claimed as a composition of matter. Appellant submits that this is a misstatement of the law and that this rejection has not been set forth on the record, and that no basis in law or fact has been given for maintaining the rejection (Appeal Brief, paragraph bridging pages 24-25). However, the basis for the rejection was given in the Office action mailed 25 July 2003, citing 64 Fed. Reg. 71427, 71428 (1999), comment No. 4. In fact, in the Appeal Brief, paragraph bridging pages 25-26, Appellant acknowledges that this citation was made. Appellant also states that the basis for this position was provided without explanation. However, the explanation was already provided to Appellant, as Appellant acknowledges in the Appeal Brief in the paragraph bridging pages 24-25.

Appellant argues that no support is found in the comment (in the Federal Register) for the position taken by the Examiner, that the comment only says that the Written Description Guidelines will address process and product-by-process claims (Appeal Brief, paragraph bridging pages 25-26). However, the comment in the Federal Register indicates that the

Guidelines should distinguish between claims to processes whose patentability depends on the compositions used in them, as opposed to those whose patentability rests in the steps of the process itself, and this suggestion was adopted. Accordingly, claim 31 includes steps in which undescribed hybrids, produced by crossing inbred corn plant I015011 with a second, different corn plant, are crossed with other undescribed corn plants. The patentability of the method of claim 31 does not lie in the method steps, which require the simple acts of crossing corn plants, allowing progeny seed to be produced, and growing progeny plants from the seed, but rather in the compositions used in the method. The method of claim 31 is not described, as the specification does not sufficiently describe the hybrid plants, for the reasons discussed above.

Appellant argues that the Written Description Guidelines are not law, and comments to the Interim Written Description Guidelines therefore do not constitute the type of support required to maintain a rejection, particularly in the face of supposedly contradicting case law submitted by Appellant (Appeal Brief, page 26, 1st full paragraph and the paragraph bridging pages 26-27). However, it is not clear what previously submitted case law Appellant is referring to, as applied to the written description rejection of claim 31. In the papers received 18 November 2002, which was in response to the first non-final action (mailed 25 September 2002), Appellant did not submit case law specifically to traverse the rejection of claim 31. In the response received 28 April 2003, which was in response to the final rejection (mailed 23 January 2003), Appellant asked that the legal basis for the rejection be provided (page 5). In supporting this request that the legal basis be provided, Appellant argued that the Examiner must present evidence to maintain a written description rejection, and cited case law, the Federal Register, and the USPTO Written Description Guidelines. This citation of case law was not for the purpose of

traversing the position taken by the Examiner, but rather in support of the request that the Examiner further substantiate his position. The Appeal Brief filed 16 October 2003 was in response to the last non-final Office action (mailed 25 July 2003) (Appellant previously submitted a first Appeal Brief on 30 June 2003. However, as explained above, the Examiner received the Appeal Brief after the mailing of the last Office action). Further, 64 Fed. Reg. 71427, 71428 (1999), Comment No. 4, states that the suggestion, that the Guidelines should distinguish between claims to processes whose patentability depends on the compositions used in them, as opposed to those where patentability rests in the steps of the process itself, has been adopted. The Examiner cited the Federal Register notice to present reasons to Appellant that method claims such as instant claim 31 are subject to rejection for lack of sufficient written descriptive support, following the Written Description Guidelines. MPEP 2163 indicates that while the Guidelines do not have the force and effect of law, they are designed to assist Office personnel in analyzing claimed subject matter for compliance with substantive law, that rejections will be based upon the substantive law, and consequently, any perceived failure by Office personnel to follow these Guidelines is neither appealable nor petitionable.

Appellant continues, arguing that what is required to meet written description is that an Applicant show that he/she was in possession of the claimed invention. Appellant argues that here a process is claimed, not a product of a process, and thus the steps of the process, not intermediate or final products, must be described (Appeal Brief, page 27, last full paragraph). However, as discussed above, the suggestion that written description of process claims in which patentability depends on the compositions used in them, as opposed to those where patentability rests in the method steps, has been adopted into the Guidelines. Appellant cites *Vas-Cath, Inc. v.*

Mahurkar in support of the argument that all that needs to be shown is that the Applicant is in possession of the claimed invention (Appeal Brief, page 27, last full paragraph). However, for the reasons discussed above regarding hybrids produced by crossing corn plant I015011 with a different undescribed corn plant, Appellant is not in possession of progeny plants produced in step (a)-(d) of claim 31. Also note that steps (c)-(d) of claim 31 requires possession of plants beyond the F1 generation of plants, and that steps (b)-(d) indicate that progeny plants of any generation can be crossed with itself or a second plant. Because Appellant is not in possession of such plants, Appellant is likewise not in possession of the methods of crossing the plants.

Appellant argues that corn breeding is well known to those of skill in the art, that without it there would not be commercial corn varieties (Appeal Brief, page 28, 2nd full paragraph). However, it is not in dispute that corn breeding is well known. Appellant argues that all of the steps of claim 31 are typical of the process used for the production of new corn varieties, save for the novelty of corn variety I015011 (Appeal Brief, page 28, 2nd full paragraph). The Examiner disagrees, and maintains that the progeny plants of steps (b)-(d) also need to be described, as written description of this process claim depends on compositions used in them, and not in the steps (the simple acts of conducting crosses and growing plants) themselves.

Claims 27-30 on appeal stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards inbred corn plant I015011 further defined as having a genome comprising any single locus conversion, encoding any trait; or wherein the single locus was stably inserted into a corn genome by transformation.

The specification teaches single locus converted plants are produced by crossing a first inbred of interest with another "donor" inbred parent plant, which contains the single locus that is to be introduced into the first inbred. The progeny of that cross is then backcrossed with the first inbred. The progeny of the backcross gets backcrossed with the first inbred several more times, until a plant is recovered that has essentially all of the desired morphological and physiological traits of the original, first inbred in addition to the trait expressed by the single locus transferred from the donor inbred plant (paragraph bridging pages 29-30). The specification at pages 35-36 provides a summary of the crosses performed to introduce a locus encoding cytoplasmic male sterility into a DEKALB proprietary inbred corn plant, designated "85DGD1." The specification does not teach any I015011 plants comprising single locus conversions produced by crossing.

A review of claim 27 indicates that it encompasses corn plant I015011, and therefore all of its morphological and physiological traits, and further comprising any single locus in its genome. The practice of crossing two plant varieties, each expressing two different desired traits, for example, to obtain a single variety that expresses both desired traits is well-established.

However, the specification does not teach any I015011 plants comprising a single locus conversion produced by backcrossing, wherein the resultant plant retains all of its morphological and physiological traits in addition to exhibiting the single trait conferred by the introduced single locus. It is not clear that single loci may be introduced into the genetic background of a plant through traditional breeding, while otherwise maintaining the genetic and morphological fidelity of the original inbred variety. Hunsperger et al. (US Patent No. 5,523, 520), Kraft et al. (Theor. Appl. Genet., 2000, Vol. 101, pages 323-326), and Eshed et al. (Genetics, 1996, Vol. 143, pages 1807-1817), for example, teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant. Hunsperger et al. teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single locus conversion plant with a desired trait (column 3, lines 26-46). Kraft et al. teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single locus conversion, and that such effects are unpredictably genotype specific and loci-dependent in nature (page 323, column 1, lines 7-15). Kraft et al. teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding materials, and therefore it is an unpredictable effect in plant breeding (page 323, column 1, lines 7-15). Eshed et al. teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816, column 1, line 1). In the

absence of further guidance, undue experimentation would be required by one skilled in the art to overcome the difficulties and unpredictability of backcross conversions taught in the prior art, in order to yield the claimed plants which differ from I015011 only in comprising a single locus conversion and by the expression of a single trait.

The specification also teaches that single loci may be introduced into a corn plant by transformation, and that methods for genetic transformation of corn were known in the prior art (page 33, lines 1-10). Claim 28 recites the recitation, "wherein the single locus was stably inserted into a corn genome by transformation" (emphasis added). This recitation does not clearly indicate that it was plant I501150 that was transformed, and the claim encompasses the embodiment that another corn plant can be transformed, wherein the single locus would be introduced into I501150 by crossing.

The specification does not enable the introduction of all types of transgenes (comprising single loci) into corn plants. As broadly interpreted, the claims encompass I015011 plants comprising any type of single locus, including those that have not been isolated at the time the application was filed, and encoding any trait. The prior art shows that hundreds of nucleotide sequences encoding products that confer various types of plant traits have been isolated at the time the instant invention was filed. One skilled in the art can transform any of these isolated nucleotide sequences known in the prior art into a corn plant cell, and regenerate a transgenic plant from the transformed cell. However, the claims do not place any limit on the single locus to be introduced. For example, isolated loci whose products confer yield enhancement or enhanced yield stability (recited in claim 30), are not known in the prior art. See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page

1021, where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence). Undue experimentation would be required by one skilled in the art to isolate single loci that govern the traits encompassed by the claims. Claims 27-29 also encompass plants with single loci whose functions are unknown. One skilled in the art would not know how to use plants containing such loci. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention. Furthermore, the effects of expression of the single locus on the traits expressed by I015011 are unknown. The specification does not teach one how to use an I015011 plant if all of the morphological and physiological traits of I015011 are not expressed. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

Appellant's arguments and Examiner's response:

Regarding the aspect of the rejection concerning the enablement of corn plants of variety I015011 comprising a single locus conversion, Appellants argue that no basis has been given to show that these references have any relevance to corn plants. Appellant argues that there is no support for the Examiner's assertion that the cited references concerning petunias, sugar beets, and tomatoes would apply to corn, and that the Action attempts to require Appellant to show why this is not true. Appellant argues that it is the burden of the Office to support its rejections (Appeal Brief, paragraph bridging pages 28-29 and the paragraph bridging pages 29-30).

However, the rejection was supported with cited references. The rejection raises the issue of how linkage drag hampers the insertion of single genes alone into a plant by backcrossing, while recovering all of the original plant's genome. Linkage drag appears to be a phenomenon that occurs in all plant types. Examples are lacking in the prior art of plants in which linkage drag does not occur. There is no evidence that corn is exempt from this universal trend. Linkage drag, for reasons embellished in the previous Office action and repeated above, would prevent one skilled in the art from making the I015011 plants comprising single locus conversions as currently claimed.

Further, the single locus may encode any product having any function, and can therefore affect the other traits expressed by I015011. For example, if the single locus encodes a transcription factor, the expression of numerous genes may be affected, which in turn would affect the traits expressed by I015011. In such a scenario, one may not obtain a plant having all or even most of the desired morphological and physiological traits of I015011, in addition to the trait conferred by the single locus.

In order to produce a single locus converted plant, a first inbred of interest is crossed with another "donor" inbred parent plant, which contains the trait that is to be introduced into the first inbred. The progeny of that cross is then backcrossed with the first inbred. The progeny of the backcross gets backcrossed with the first inbred several more times, until a plant is recovered that has essentially all of the desired morphological and physiological traits of the original, first inbred in addition to the trait (single locus) transferred from the donor inbred parent (specification, paragraph bridging pages 29-30). The claims, however, broadly encompass plants that comprise exactly the genome of I015011, further comprising just a single additional locus.

While the introduction of a desired trait from one plant into another using crossing techniques is well known in the prior art, what is not clear is that a plant that has exactly the same genome as I015011 is recovered, in addition to the introduced single locus. The claims encompass such plants. The very first cross involves crossing I015011 to another plant and results in a plant that expresses traits that are very different from those expressed by I015011, due to the presence of the genetic material from the non-I015011 plant. It is not clear, despite repeated backcrossing with I015011, that a plant having the exact same genome of I015011 can be recovered (in addition to the introduced single locus), particularly in view of the genetic linkage of multiple genes conferring multiple additional traits, as established by the cited references. The specification attempts to address this by indicating that "essentially" all of the "desired" morphological and physiological traits of an inbred are recovered, in addition to the transferred single locus (paragraph bridging pages 27-28). However, the claims are directed to exactly plant I015011 further comprising the single locus.

Appellant argues that the Examiner further disregarded the example of a conversion that was made with a proprietary corn variety by stating that information has been left out, such as the number of crosses that were performed at each step. Appellant argues that no such steps are left out (Appeal Brief, page 29 1st full paragraph). However, the Examiner did not make any such allegation that a number of crosses were left out. Rather, the rejection raised the issue that there is no indication that all of the morphological and physiological traits of the DEKALB proprietary inbred corn plant were recovered, and that only one single locus was transferred from the donor parent.

The rejection also raised the issue that claims 28-30 broadly encompass corn plants comprising any type of single loci, encoding any trait, including those that have not yet been identified or isolated. The claims are not enabled for plants comprising such unknown loci. Appellant does not address this issue in the Appeal Brief. For example, single loci that alone confer the trait of yield enhancement or enhanced yield stability, recited in claim 30, are unknown. The Examiner would like to point out that he is not requiring Appellant to identify each and every single loci or transgene by name. It is suggested that claims 27-30 be amended to indicate the type of single locus, not any specific single locus by name, contemplated by the specification. For example, many herbicide resistance genes or plant disease resistance genes were known in the prior art. Claim 30 already does this, but also recites traits that are not conferred by single loci. If the isolated gene (or single locus) is taught and known in the prior art, one skilled in the art would know how to make and use the claimed plant.

The Examiner would also like to note that, prior to the submission of the Appeal Brief of 14 October 2003 by Appellants, Supervisory Patent Examiner Amy Nelson faxed to Appellant a proposed, generic set of claim amendments that, after being rewritten to be particularly drawn towards the instant invention, would place the application in condition for allowance. The proposed claims particularly address the subject matter of, and would replace, pending claims 16 and 27-30, which are drawn towards I015011 plants further comprising a nuclear or cytoplasmic

gene conferring male sterility, or I015011 plants further comprising a single locus conversion, or wherein the single locus was stably inserted into a corn genome by transformation. However, a response to the offer was never received from the Appellant for this application. The proposed claim amendments, as they would apply to the instant application, are provided below in Appendix A. Regarding the proposed claims 32-41, directed towards methods comprising transforming corn plant I015011: the method is considered acceptable to the Examiner because it indicates the traits that would be affected by the transgene (a single locus), or it recites the type of transgene that is intended to be introduced into the plant. Of course, Appellant would not be limited to only those traits mentioned in the proposed claims. Any such trait may be recited, provided that there is written descriptive support in the specification and the prior art teaches that genes or single loci that affect such traits have been isolated. It is again noted that the Examiner is not requiring that the claims recite the actual names of any genes. Regarding the proposed claims 42-46, drawn towards a method of introducing a desired trait into the inbred plant of the invention using backcrossing techniques (which would result in plants comprising a single locus conversion, to use the terminology of the instant application): the proposed method claims are considered acceptable because they 1) indicate the types of traits that are contemplated, and 2) indicate that, after the inbred plant of the invention is crossed with a plant that contains the desired trait to be transferred, the progeny plant is to be backcrossed and selected at least four times, to ensure that undesirable genetic material from the donor plant is lost and that the resultant plant will also recover all of the traits of the original plant that are taught in Table 3 of the specification. It is important that the resultant plant retain the traits recited in Table 3, as it is this combination of traits that make inbred corn plant I015011 novel and described. Note that

the proposed method claim does not require the recovery of I015011 traits that are absent from Table 3. The method of the proposed claim results in a plant having the traits of I015011 recited in Table 3, in addition to the introduced trait.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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Appendix A- Proposed New Claims

32. A method of producing a male sterile corn plant comprising transforming the corn plant of claim 5 with a nucleic acid molecule that confers male sterility.

33. A male sterile corn plant produced by the method of claim 32.

34. A method of producing an herbicide resistant corn plant comprising transforming the corn plant of claim 5 with a transgene that confers herbicide resistance.

35. An herbicide resistant corn plant produced by the method of claim 34.

36. The corn plant of claim 35, wherein the transgene confers resistance to an herbicide selected from the group consisting of glyphosate, sulfonylurea, and phosphinothricin.

37. A method of producing an insect resistant corn plant comprising transforming the corn plant of claim 5 with a transgene that confers insect resistance.

38. An insect resistant corn plant produced by the method of claim 37.

39. The corn plant of claim 38, wherein the transgene encodes a *Bacillus thuringiensis* Bt toxin.

40. A method of producing a disease resistant corn plant comprising transforming the corn plant of claim 5 with a transgene that confers disease resistance.

41. A disease resistant corn plant produced by the method of claim 40.

42. A method of introducing a desired trait into corn inbred line I015011 comprising:

(a) crossing I015011 plants grown from I015011 seed, representative seed of which has been deposited under ATCC Accession No. PTA-3224, with plants of another corn line that comprise a desired trait to produce F1 progeny plants, wherein the desired trait is selected from the group consisting of male sterility, herbicide resistance, insect resistance, and disease resistance;

(b) selecting F1 progeny plants that have the desired trait to produce selected F1 progeny plants;

(c) crossing the selected progeny plants with the I015011 plants to produce backcross progeny plants;

(d) selecting for backcross progeny plants that have the desired trait and traits of corn inbred line I015011 listed in Table 3 to produce selected backcross progeny plants; and

(e) repeating steps (c) and (d) three or more times in succession to produce selected fourth or higher backcross progeny plants that comprise the desired trait and all of the traits of corn inbred line I015011 listed in Table 3 as determined at the 5% significance level when grown in the same environmental conditions.

43. A plant produced by the method of claim 42, wherein the plant has the desired trait and all of the traits of corn inbred line I015011 listed in Table 3 as determined at the 5% significance level when grown in the same environmental conditions.

44. The plant of claim 43 wherein the desired trait is herbicide resistance and the resistance is conferred to an herbicide selected from the group consisting of: sulfonylurea, glyphosate, and phosphinothricin.

45. The plant of claim 43 wherein the desired trait is insect resistance and the insect resistance is conferred by a transgene encoding a *Bacillus thuringiensis* Bt toxin.

46. The plant of claim 43 wherein the desired trait is male sterility and the trait is conferred by a nucleic acid that confers male sterility.